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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,437	12/21/2000	Gregory S. Hamilton	23758	7495

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NATH & ASSOCIATES
1030 15th STREET
6TH FLOOR
WASHINGTON, DC 20005

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.



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EXAMINER

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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on December 13, 2001
- ☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or 30 days~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-5 are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-5 are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

Claims 1-5 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the phrase "active truncated derivatives thereof" found in claim 5. Therefore, the metes and bounds of the claim cannot be ascertained.

Response to Arguments concerning 112 rejections

Applicant argues that the claim is not indefinite because it is broad. In response, the claim has not been found indefinite because of its

breadth. The claim is indefinite because it is unclear what the phrase "active truncated derivatives thereof" embraces. The instant specification fails to define this phrase. Applicant has failed to specify in their remarks where in the instant specification where this phrase to defined. Therefore, the metes and bounds of the claim cannot be ascertained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Moloney et al. {J. Med. Chem., July 15, 1999, Volume 42, pages 2504-2526 - on 1449 Form}.

Moloney et al. disclose compounds 78 and 79 on page 2508 which are embraced by instant claim 1.

Applicants argue that Moloney et al. disclose compounds 78 and 79 only as intermediates with no suggested or recognized pharmaceutical properties and therefore, Moloney et al. do not enable the instant invention. In response, claim 1 is directed to compounds. Moloney et al. disclose compounds embraced by instant claim 1 (compare Moloney et al.'s compound 78 and instant claim 1 wherein each X is oxygen, D is a C₂ alkyl and R is a phenyl which is substituted by a nitro group). Therefore, instant claim 1 is anticipated by Moloney et al.

The rejections of the claims under 35 USC § 102(b) and § 103 over Takai et al. (U.S. Pat. 4,668,683) has been withdrawn. Therefore, any arguments pertaining to this reference will not be addressed.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by:

- A) Imbach et al., CA 60:2923b, 1964 {CA Registry Number 97359-06-3} – listed on 1449 Form (claim 1 is anticipated);
- B) Wakabayashi et al., JP 52083686 {for instance, Examples 1, 30, etc. on pages 880 and 882, respectively} (claim 1 is anticipated);
- C) GB 1,503,244 {for instance, Example 1(A) on page 6} (claims 1 and 3 are anticipated);
- D) Liao et al., CA 102 :6312, 1985 {CA Registry Number 92763-94-5} - listed on 1449 Form (claim 1 is anticipated);
- E) Jamieson et al., U.S. Pat. 4,230,709 {for instance, Example 8 in column 5} – listed on 1449 Form (claims 1 and 3);
- F) Lopez Rodriquez et al., WO 96/06846 {for instance, compound 1g on page 4, lines 9-10 (CA Registry Number 178481-97-5)} – listed on 1449 Form; (claims 3-5) and

G) Lopez-Rodriguez, J. Med. Chem., May 23, 1997, Volume 40, pages 1648-1656 {see, for instance, Compound 1a in Table 1 on page 1650} – listed on 1449 Form (claim 3).

Each of the above cited references disclose products that are embraced by the instant claims.

Response to Arguments concerning 102(b) rejections

A) Imbach et al.

Applicant argues that the Office Action does not specify any particular compound in Imbach et al. that is embraced by the instant claims. In response, the Office Action states that the claim is anticipated by CA Registry Number 97359-06-3. This registry number identifies a specific compound which is found in the Imbach et al. reference and that compound is N-octyl-1,2-pyrrolidinedicarboximide that is embraced by instant claim 1 wherein X is oxygen, D is a C₇ alkyl and R is hydrogen.

B) Wakabayashi et al.

Applicant argues that Wakabayashi et al. do not cite any pharmaceutical properties. In response, Applicant claims compounds. Wakabayashi et al. disclose compounds that are embraced by instant claim 1. See the table starting on page 880, and, for instance, Example 1.

C) GB 1,503,244

Applicant argues that this GB reference does not cite any suggested or recognized pharmaceutical properties and therefore the rejection should be withdrawn. In response, Applicant claims a pharmaceutical composition comprising a compound of the instant formula and a pharmaceutically acceptable carrier. The GB reference discloses compounds embraced by instant claims that are added to carriers or diluents such as kaolin and talc (page 17, lines 39-44). Kaolin and talc are known to be diluents/carriers in the pharmaceutical arts (see Jamieson et al. – U.S. Pat. 4,230,709 – column 3, lines 64-68 and column 4, lines 1-16). Further, the GB states ethanol (page 17, lines 39-42) as a carrier

which Applicant also uses in his compositions (Example 21, page 66, line 26). Therefore, the rejection is maintained.

D) Liao et al.

Applicant argues that the Office Action does not specify any particular compound in Liao et al. that is embraced by the instant claims. In response, the Office Action states that the claim is anticipated by CA Registry Number 92763-94-5. This registry number identifies a specific compound which is found in the Liao et al. reference and that compound is tetrahydro-2-[3-(3-1H-pyrrolo[1,2-c]imidazole-1,3(2H)-dione that is embraced by instant claim 1 wherein X is oxygen, D is a C₃ alkyl and R is a 4-methoxyphenyl group.

E) Jamieson et al.

Applicant argues that Jamieson et al. do not cite any suggested or recognized pharmaceutical properties. In response, Jamieson et al. disclose compounds and compositions embraced by the instant claims

which are useful in treating hypersensitivity conditions such as asthma (column 1, lines 1-12; column 3, lines 18-68; and column 4, lines 1-16 and Example 8 in column 5).

F) Lopez Rodriquez {WO 96/06846}

Applicant argues that the Office Action does not specify any particular compound in Lopez Rodriquez et al. that is embraced by the instant claims. In response, the Office Action states that the claims are anticipated by CA Registry Number 178481-97-5. This registry number identifies a specific compound which is found in the Lopez Rodriquez et al. reference and that compound is tetrahydro-2-[(4-phenyl-1-piperazinyl)methyl]-1H-pyrrolo[1,2-c]imidazole-1,3(2H)-dione dihydrochloride {compound 1g on page 4, lines 9-10 } that is embraced by instant claim 3 wherein X is oxygen, D is a C₁ alkyl and R is a phenyl substituted mono-cyclic heterocyclic group.

Applicant argues that Lopez Rodriquez et al. do not cite any suggested or recognized pharmaceutical properties and therefore the

rejection should be withdrawn. In response, Lopez Rodriquez et al. disclose compounds and compositions embraced by instant claims 3-5 which have an affinity for the serotonergic receptor 5-HT_{1A} and are useful in treating central nervous system (CNS) disorders (see abstract).

G) Lopez-Rodriquez {J. Med. Chem.}

Applicant also argues that Lopez-Rodriquez et al. do not cite any suggested or recognized pharmaceutical properties. In response, Lopez-Rodriquez et al. teach that the compounds have an affinity for 5-HT_{1A} receptors. As stated in the previous art of Lopez-Rodriquez, compounds which have an affinity for the receptor 5-HT_{1A} are useful in treating central nervous system disorders. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a

person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakabayashi et al. {JP 52083686}, GB 1,503,244, Jamieson et al. {U.S. Pat. 4,230,709} and Lopez Rodriquez {WO 96/06846}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims hydantoin products. Each of Wakabayashi et al. (page 877), GB 1,503,244 (page 2, Formula I), Jamieson et al. (column 1, Formula I) and Lopez Rodriquez (pages 1 and 2) teach hydantoin products which are structurally similar to the instant claimed products.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. treating central nervous system disorders).

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would thus be motivated to prepare compounds embraced by the reference genera to arrive at the instant claimed products with the expectation of obtaining compounds which would be useful, for example, in treating central nervous system disorders. Therefore, the instant claimed invention would have been suggested to one skilled in the art.

Response to Arguments concerning 103 rejections

Applicant argues that: (1) Lopez Rodriquez et al. do not teach products of the same general formulas as claimed in the instant specification; (2) there is no suggestion in any of the cited art that the claimed compositions have any pharmaceutical properties; and (3) there is no incentive in the prior art references for one of ordinary skill in the art to prepare the claimed compounds.

All of Applicant's arguments have been considered but have not been found persuasive. Lopez Rodriquez et al. do teach products by the instant claims. See in the reference, for example, compound 1g on page 4, lines 9-10 which is tetrahydro-2-[(4-phenyl-1-piperazinyl)methyl]-1H-pyrrolo[1,2-c]imidazole-1,3(2H)-dione dihydrochloride. Jamieson et al. teach that their hydantoins are used to treat asthma (column 1, lines 1-12) and Lopez Rodriquez et al. teach that their compounds are useful in treating central nervous system (CNS) disorders (see abstract). Further, one skilled in the art would have been motivated to prepare additional products embraced by the reference genera. See in particular, for instance, Example 1(A) on page 6 of GB 1,503,244 and the third compound in instant claim 2 on page 79, lines 26-27. Therefore, the instant claimed products would have been suggested to one skilled in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

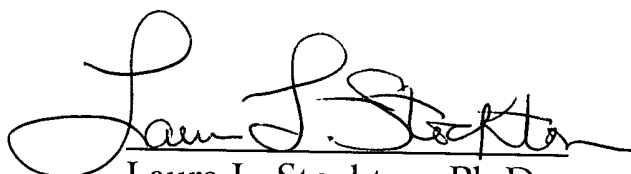
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Application/Control Number: 09/741,437
Art Unit: 1626

Page 15

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235, 308-0196 or 305-3290.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556, 308-4242, 305-1935 or 308-2742.

A handwritten signature in cursive script, reading "Laura L. Stockton". The signature is written in black ink and is positioned above the printed name.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

January 4, 2002